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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,667	12/06/2001	Daniel E. Afar	511582001601	1346

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EXAMINER

NICKOL, GARY-B

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 04/15/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/010,667

Applicant(s)

AFAR ET AL.

Examiner

Gary B. Nickol Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claims 40-47 are pending and are currently under consideration.

Information Disclosure Statement

The information disclosure statement filed 1-23-03 fails to comply (in part) with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is *not* in the English language (See **JP11164691-A**). It has been placed in the application file, but the information referred to therein has not been considered.

Drawings

The corrected or substitute drawings were received on 04-04-2002. These drawings are acceptable.

Priority

Claims 40-47 are given a priority date of June 1, 1999 as there is no clear support in the provisional applications for residues 14-28 of SEQ ID NO:2, SEQ ID NO:19, SEQ ID NO:20, and SEQ ID NO:21. If applicant disagrees with any rejection set forth below, applicant is invited

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to submit evidence pointing to the serial number, page and line where support can be found establishing an earlier priority date.

Specification

The specification is objected to for the following reason: The specification on page 1 should be amended to reflect the priority status of the present application, for example:

This application is a Continuation of U.S. Serial No. 09/323,873 filed 1 June 1999, now US Patent No. 6,329,503. Also, applicant should amend the specification on pages 49-50- moving the provisional information to page 1 of the specification.

The specification is objected to because it contains embedded hyperlinks and/or other forms of browser-executable code (i.e. see page 7, lines 30 and 32; also see page 48). Applicant is requested to delete all embedded hyperlinks and/or other form of browser-executable codes. See MPEP § 608.01

Also, applicant is requested to clarify the vector numberings on page 48. For example, are the numerals on page 48, lines 3-4 correct? What do they represent?

The specification is further objected to on page 36, line 5 for reciting "RSACDN" in association with an oligonucleotide. Is this a trademark? Clarification is requested.

The abstract is objected to for referring to "STRAP" polypeptides because the claims and specification are drawn to peptides derived from STEAP1.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 40-47, as written, do not sufficiently distinguish over proteins as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified" See MPEP 2105.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 40-41, and 46 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 40-42, and 44 of copending Application No. 10/011095. Although the conflicting claims are not identical, they are not patentably distinct from each other because the Board of Patent Appeals and interferences has taken the position that once an antigen has been isolated, the manufacture of monoclonals

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antibodies against it is *prima facie* obvious. See *Ex parte Ehrlich*, 3 USPQ 2d 1011 (PTO Bd. Pat. App. & Int. 1987), *Ex parte Sugimoto*, 14 USPQ 2d 1312 (PTO Bd. Pat. App. & Int. 1990).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 40-47 are also rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6329503. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are drawn to the genus of polypeptides comprising SEQ ID NO:2 including a heterologous polypeptide, detectable markers, and a carrier, all of which encompass the pending claims drawn to species of selected peptides of SEQ ID NO:2.

Applicants allege (Paper No. 12, page 3) that a terminal disclaimer with respect to the parent application has been filed; however, it appears that no terminal disclaimer has been filed with the papers received in Paper No. 12.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 40, and 42-45 are rejected under 35 U.S.C. 102(a) as being anticipated by Abu-Threideh *et al.* EMBL/GENBANK/DDBJ DATABASES, June 1998.

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Abu-Threideh *et al.* teach a heterologous peptide having the amino acid sequence of SEQ ID NO:19, SEQ ID NO:20, and SEQ ID NO:21 (see attached sequence listings).

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
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GBN
April 11, 2003

